



PATENT
ATTORNEY DOCKET No.: SP01-371

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Matthew J. Dejneka et al.
Serial No: 10/027,286
Filing Date: 12/20/2001
Title: DETECTABLE LABELS,
METHODS OF
MANUFACTURE AND USE

Examiner: Pensee T. Do
Group Art Unit: 1641

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

This Brief supports the appeal to the Board of Patent Appeals and Interferences from the final rejection dated July 13, 2005, in the application listed above. Appellant filed the Notice of Appeal on *September 9, 2005*. Appellant now submits this Brief as required by 37 C.F.R. § 41.37.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is Corning Incorporated.

II. RELATED APPEALS AND INTERFERENCES

With respect to the related appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal, there are no such appeals or interferences.

III. STATUS OF CLAIMS

On July 13, 2005, the Examiner issued a Final Office Action which allowed the subject matter of claims 5-15, 19, 20, 22-25, pending compliance with the written description

requirement, and rejected claims 1-3, 16-17. The Examiner stated that "Applicant's arguments filed on April 8, 2005 are not persuasive".

On *September 9, 2005* appellant appealed from the final rejections of claims 1, 3, 16-17 which were rejected in the final Office Action dated July 13, 2005. Claims 1, 3, 5-17, 19, 20, and 22-25 are the pending claims and are set forth in the attached Appendix. Claims 1, 3, 5-17, 19, 20, and 22-25 are the subject of this Appeal.

IV. STATUS OF AMENDMENTS

The appellant is filing an amendment making a minor correction to claim 1 concurrently with this appeal brief. Claims 1, 3, 5-17, 19, 20 and 22-25 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claim 1 was rejected as being indefinite for reciting the term "adapted to." The objectionable language has been deleted. For the reasons explained, appellant believes that that amendment is entitled to entry under the standards set forth in MPEP §1207.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to a novel glass particle 10 used as a label with the capability of enhancing detection of biomolecules and biomolecular interactions (See specification p.8, ¶[00028]). Biochemical assays presently allow multiplexing and miniaturization of tests by providing unique targets within individual wells of a microtiter plate. Another way of multiplexing is through the use of labeled beads/particles. The use of labeled particles together with microtiter plates facilitates the design of highly multiplexed assays involving the binding of many different probes to many different particle types within

individual wells. Glass particles provide significant advantages over currently milled microparticles. The unique coding of the glass particles proves superior detection capability and allows for any number of identifiably distinct labels with a given assay. The improved invention includes a glass core particle coded with a rare earth element(s) (p.3, ¶[0009]) and is specifically designed to be utilized in conventional detection methods (p. 3, ¶[0008]; p.9, ¶[00030]).

Claim 1 relates to a glass particle doped with a rare earth element to provide “a unique identification code to identify a functional group attached thereto”. The glass particle of claim 1 has “a diameter of between 10 microns and 100 microns”. Glass particles having a diameter “on the order of about 10 to 100 microns” are discussed, for example, in paragraph [00032] (p.10, lines 12-16).

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The claims are currently rejected by the Patent Office as follows:

Claims 1, 3, 5-17, 19, 20, 22-25 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Claims 1, 3, 16-17 are rejected under 35 U.S.C. §102(e) as being unpatentable over Kardos et al (US Patent No. 6,159,686).

VII. ARGUMENT

The rejection of Claims 1, 3, 5-17, 19, 20, 22-25 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement is improper.

As distinctly stated in 35 U.S.C. §112:

The specification shall contain a written description of the invention, and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall

set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 recites a limitation “whereby the particle has a diameter of between 10 microns and 100 microns”. The particles are cut from an elongated glass structure (p. 9, ¶[00030]); the particles of which “have a diameter of about 10 to 100 microns” (p. 10, ¶[00032]). Therefore, it is clear from the specification that the particles will necessarily have a diameter commensurate with the diameter of the fiber from which they were cut (i.e. 10-100 microns). The fabrication of the glass particle utilized as a detectable label would enable any person skilled in the art to make and use the glass particle of the present invention.

The rejection of Claims 1, 3, 16-17 under 35 U.S.C. §102(e), as being unpatentable over Kardos et al is improper.

A proper *prima facie* showing of anticipation requires the prior art relied upon to teach every element of the claim (MPEP §2131). “The identical invention must be shown in as complete detail as is contained in the claim.” See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The Examiner has rejected Claims 1, 3, 16-17 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,159,686 (Kardos). In order to attempt to satisfy the requirements for establishing a *prima facie* case of anticipation under 35 U.S.C. § 102, the Examiner asserts that the limitation in Applicant’s claim 1, reciting “whereby the particle has a diameter of between 10 microns and 100 microns”, is satisfied by the following statement from the Kardos reference: “The phosphor particles have a diameter of about 0.01 to 3 microns and larger or smaller particles can be used.” (Final Office Action, 07/13/2005, Application No. 10/027,286, Paper No. 070605). Although Kardos indeed offers that

particles larger than 3 microns may be used, there is no indication that particles in the range of 10-100 microns as claimed by Applicant (i.e. approximately 3-33 times larger than the largest of those which Kardos suggests) are what Kardos had intended. In fact, Kardos suggests that particles smaller than 3 microns are more advantageous for his intended purpose of detecting an analyte using an up-converting particle and a luminescent label (Kardos, col. 13, lines 43-52).

The MPEP establishes that a prior art reference that is close to, but does not touch the claimed range may not be used as an anticipatory reference. MPEP §2131.03 (III), recites as follows:

PRIOR ART WHICH TEACHES A VALUE OR RANGE THAT IS VERY CLOSE TO,
BUT DOES NOT OVERLAP OR TOUCH, THE CLAIMED RANGE DOES NOT
ANTICIPATE THE CLAIMED RANGE.

“Anticipation under §102 can be found only when the reference discloses exactly what is claimed . . .” (*Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)). As noted, the Kardos reference does not disclose exactly what is claimed. Not only does the Kardos reference fail to touch the claimed range, the only particle sizes that it discloses are not even close to the claimed range.

Applicants therefore submit that by failing to provide a reference that teaches the claimed particle range, the Examiner has failed to establish a *prima facie* case under 35 U.S.C. §102 and that the rejection is therefore improper.

Conclusion

In conclusion, Appellants request a reversal of each of the grounds of rejection

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maintained by the Examiner and prompt allowance of the rejected claims 1, 3, 5-17, 19, 20 and 22-25.

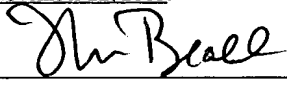
Please charge the fees due under 37 C.F.R. § 1.17(c) to Deposit Account No. 03-3325.

If there are any other fees due in connection with the filing of this Brief on Appeal, please charge the fees to our Deposit Account No. 03-3325. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: November 22, 2005

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<p>CERTIFICATE OF MAILING (37 CFR 1.8a)</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope Addressed to: Mail Stop Appeal Brief, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on <u>November 22, 2005</u>.</p> <p><u></u></p> <p>Thomas R. Beall</p>

VIII. CLAIMS APPENDIX

The claims on appeal are as follows:

1. (Previously amended) A detectable label comprising a glass particle doped with at least one rare earth element, the glass particle further providing a unique identification code ~~adapted to~~ to identify a functional group attached thereto, wherein the functional group is selected from the group consisting of a nucleic acid, an antibody, a protein, and an enzyme, and wherein the rare earth element is selected from the group consisting of Ce, Pr, Nd, Sm, Eu, Gd, Tb, Dy, Ho, Er, Tm, Yb, U, and combinations thereof, and

whereby the particle has a diameter of between 10 microns and 100 microns.

2. (Cancelled) The label of claim 1, wherein the rare earth element is selected from the group consisting of Ce, Pr, Nd, Sm, Eu, Gd, Tb, Dy, Ho, Er, Tm, Yb, U, and combinations thereof.

3. (Previously amended) The label of claim 1, wherein the particle includes a plurality of rare earth elements arranged in a pattern or array to provide the unique identification code for the particle.

4. (Cancelled) The label of claim 3, wherein the label is adapted to detect an analyte in a sample or interaction of two molecules.

5. (Original) The label of claim 3, wherein the particle includes a glass microparticle having a pattern of rare earth elements shutter masked thereon.

6. (Previously amended) The label of claim 3, wherein the particle is a fiber having a cross-section including an array of layers, each of the layers having an optical property different from an optical property of adjacent layers.

7. (Original) The label of claim 6, wherein the fiber includes materials selected from the group consisting of inorganic materials, glasses, polymers and combinations thereof.

8. (Original) The label of claim 6, wherein the layers are arranged concentrically.

9. (Original) The label of claim 6, wherein the layers are arranged across a cross section of the fiber.

10. (Original) The label of claim 9, wherein one of the layers varies in thickness from the other layers.

11. (Original) The label of claim 8, wherein one of the concentric layers varies in thickness from the other layers.

12. (Original) The label of claim 6, wherein the layers are arranged concentrically, and each concentric layer has a spectral emission different from the spectral emission of adjacent concentric layers.

13. (Original) The label of claim 6, wherein the particle is made from glass, the layers are arranged across a cross section of the fiber and at least one of the layers has a spectral emission different from the spectral emission of the other layers in the particle.

14. (Previously amended) The label of claim 6, wherein the particle includes a chemical functional group attached thereto for interaction with an analyte or biomolecule.

15. (Original) The label of claim 14, wherein the particle includes a surface treatment to facilitate binding or attachment of biomolecules thereto.

16. (Original) The label of claim 1, wherein the particle includes a surface treatment to facilitate binding or attachment of biomolecules thereto.

17. (Previously amended) The label of claim 3, wherein the label includes the functional group attached thereto for interaction with an analyte or biomolecule.

18. (Cancelled) The label of claim 17, wherein the chemical functional group is selected from the group consisting of a nucleic acid, an antibody, a protein, and an enzyme.

19. (Previously amended) The label of claim 6, wherein the layers are arranged in a manner that can be used to identify the functional group.

20. (Original) The label of claim 6, wherein the particle includes a chemical or biological functional group attached thereto for interaction with the analyte.

21. (Cancelled) The label of claim 20, wherein the chemical functional group is selected from the group consisting of a nucleic acid, an antibody, a protein, and an enzyme.

22. (Previously amended) The label of claim 6, wherein the layers are arranged in a manner that can be used to identify the functional group.

23. (Original) The label of claim 22, wherein the fiber is made from glass, and the layers are doped with elements selected from the group consisting of Ce, Pr, Nd, Sm, Eu, Gd, Tb, Dy, Ho, Er, Tm, Yb, U, and combinations thereof.

24. (Original) The label of claim 6, wherein the fiber has a cross-sectional dimension of less than 1 millimeter.

25. (Original) The label of claim 3, wherein the particle is derived from a cross-section plurality of fibers arranged in a bundle, and at least one of the fibers including a rare earth dopant different from the rare earth dopant contained in at least one of the other fibers in the bundle.

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IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None